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Counterclaim Plaintiffs
Dr. Reddy's Laboratories, Ltd. and
Dr. Reddy's Laboratories, Inc.*

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

ASTRAZENECA AB, ASTRAZENECA LP,
and POZEN INC.,

Plaintiffs,

v.

DR. REDDY'S LABORATORIES, LTD. and
DR. REDDY'S LABORATORIES, INC.,

Defendants

Civil Action No. 3-11-cv-02317 (JAP)(LHG)

ELECTRONICALLY FILED

**ANSWER OF DR. REDDY'S LABORATORIES, LTD. AND
DR. REDDY'S LABORATORIES, INC. AND COUNTERCLAIMS**

Defendants Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc.
(collectively "DRL") by their attorneys, for their answer to the Complaint by AstraZeneca AB,
AstraZeneca LP, and Pozen Inc., (collectively, "AstraZeneca" or "Plaintiffs") respond to
allegations as follows:

Nature of the Action

1. DRL admits that this action is for patent infringement.

The Parties

2. DRL admits the allegations contained in paragraph 2 of the Complaint.
3. DRL admits the allegations contained in paragraph 3 of the Complaint.
4. DRL admits the allegations contained in paragraph 4 of the Complaint.
5. DRL admits the allegations contained in paragraph 5 of the Complaint.
6. DRL admits the allegations contained in paragraph 6 of the Complaint.
7. DRL admits the allegations contained in paragraph 7 of the Complaint.

BACKGROUND

The NDA

8. DRL admits the allegations contained in paragraph 8 of the Complaint.
9. DRL denies the allegations contained in paragraph 9 of the Complaint.

The Patent in Suit

10. DRL denies the allegations of paragraph 10 of the Complaint, except admits that the U.S. Patent No. 6,926,907 (“the ‘907 patent”), entitled “Pharmaceutical Compositions for the Coordinated Delivery of NSAIDs,” issued on August 9, 2005, and that the Complaint annexes a copy of the ‘907 patent as Exhibit A.

11. DRL lacks information or knowledge sufficient to admit or deny the allegations set forth in paragraph 11 of the Complaint, except that DRL admits that the ‘907 patent states on its face that the assignee of the patent is Pozen Inc.

The ANDA

12. DRL admits the allegations contained in paragraph 12 of the Complaint.

13. DRL admits the allegations contained in paragraph 13 of the Complaint.

JURISDICTION AND VENUE

14. DRL admits the allegations contained in paragraph 14 of the Complaint.

15. DRL admits the allegations contained in paragraph 15 of the Complaint.

16. DRL admits jurisdiction and venue in this case per Acknowledgment of Service and Stipulation executed on April 27, 2011 (DE 9) and denies the remaining allegations in paragraph 16 of the Complaint.

17. DRL admits jurisdiction and venue in this case per Acknowledgment of Service and Stipulation executed on April 27, 2011 (DE 9) and denies the remaining allegations in paragraph 17 of the Complaint.

18. DRL admits jurisdiction and venue in this case per Acknowledgment of Service and Stipulation executed on April 27, 2011 (DE 9) and denies the remaining allegations in paragraph 18 of the Complaint.

19. DRL admits jurisdiction and venue in this case per Acknowledgment of Service and Stipulation executed on April 27, 2011 (DE 9) and denies the remaining allegations in paragraph 19 of the Complaint.

20. DRL admits the allegations contained in paragraph 20 of the Complaint.

21. DRL admits the allegations contained in paragraph 21 of the Complaint.

22. DRL admits the allegations contained in paragraph 22 of the Complaint.

23. DRL admits jurisdiction and venue in this case per Acknowledgment of Service and Stipulation executed on April 27, 2011 (DE 9) and denies the remaining allegations in paragraph 23 of the Complaint.

24. DRL admits jurisdiction and venue in this case per Acknowledgment of Service and Stipulation executed on April 27, 2011 (DE 9) and denies the remaining allegations in paragraph 24 of the Complaint.

25. DRL admits jurisdiction and venue in this case per Acknowledgment of Service and Stipulation executed on April 27, 2011 (DE 9) and denies the remaining allegations in paragraph 25 of the Complaint.

26. DRL admits jurisdiction and venue in this case per Acknowledgment of Service and Stipulation executed on April 27, 2011 (DE 9) and denies the remaining allegations in paragraph 26 of the Complaint.

27. DRL admits jurisdiction and venue in this case per Acknowledgment of Service and Stipulation executed on April 27, 2011 (DE 9) and denies the remaining allegations in paragraph 27 of the Complaint.

28. DRL admits jurisdiction and venue in this case per Acknowledgment of Service and Stipulation executed on April 27, 2011 (DE 9) and denies the remaining allegations in paragraph 28 of the Complaint.

29. DRL admits jurisdiction and venue in this case per Acknowledgment of Service and Stipulation executed on April 27, 2011 (DE 9) and denies the remaining allegations in paragraph 29 of the Complaint.

COUNT I
(INFRINGEMENT OF THE '907 PATENT UNDER 35 U.S.C. § 271 (e)(2)(A))

30. DRL incorporates and repeats its responses to paragraphs 1-29 above as if set forth here.

31. DRL admits the allegations contained in paragraph 31 of the Complaint.

32. DRL admits the allegations contained in paragraph 32 of the Complaint.

33. DRL denies the allegations contained in paragraph 33 of the Complaint, except that DRL admits that filing of its ANDA constituted a “technical” act of infringement pursuant to 35 U.S.C. § 271(e) (2).

34. DRL denies the allegations contained in paragraph 34 of the Complaint.

35. DRL denies the allegations contained in paragraph 35 of the Complaint.

36. DRL denies the allegations contained in paragraph 36 of the Complaint.

PRAYER FOR RELIEF

37. DRL denies that Plaintiffs are entitled to judgments and relief prayed for in paragraphs A through F of the Complaint.

AFFIRMATIVE DEFENSES

38. DRL alleges and asserts the following affirmative defenses in response to the allegations in AstraZeneca’s Complaint:

First Affirmative Defense

39. The manufacture, use, offer for sale, sale or importation of the product described in DRL’s ANDA 202461 does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid or enforceable claim of the ‘907 patent.

Second Affirmative Defense

40. At least claims 1, 5, 9-17, 21-24, 28-29, 32-35, 37, 41-42, 45-48, and 50-55 of the ‘907 patent are invalid under Title 35 United States Code, including, *inter alia*, §§101, 102, 103, 112, and for double patenting.

Third Affirmative Defense

41. The manufacture, use, sale, offer to sell in the United States or the importation into the United States of DRL's proposed product does not and would not infringe at least claims 2-4, 6-8, 18-20, 25-27, 30-31, 36, 38-40, 43-44, and 49.

Fourth Affirmative Defense
(Prosecution History Estoppel)

42. The claims of the '907 patent are so limited as not to cover the manufacture, use, offer for sale, sale or importation of the product described in DRL's ANDA 202461 due to the arguments, statements, representations and/or amendments made by Plaintiffs to the United States Patent and Trademark Office during the prosecution of the application leading to issuance of the '907 patent.

Fifth Affirmative Defense

43. Each of Plaintiffs' allegations of infringement of the '907 patent under 271(a), (b), and/or (c) fails to state a claim upon which relief can be granted.

COUNTERCLAIMS

44. Defendants/Counterclaimants Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. (collectively "DRL") by their attorneys, for their counterclaims against AstraZeneca AB, AstraZeneca LP, and Pozen Inc., (collectively, "Counterclaim Defendants or "AstraZeneca") allege and aver as follows:

PARTIES

45. Counterclaim Plaintiff Dr. Reddy's Laboratories, Ltd. is an Indian corporation, with its principal place of business at 8-2-337 Road No. 3, Banjara Hills, Hyderabad, 500034, India.

46. Counterclaim Plaintiff Dr. Reddy's Laboratories, Inc. is a New Jersey corporation, with its principal place of business at 200 Somerset Corporate Boulevard, Bridgewater, New Jersey.

47. Counterclaim Defendant AstraZeneca AB is a corporation existing under the laws of Sweden, with its principal place of business at S-151 85 Södertälje, Sweden. (*See* DE 1, ¶2).

48. Counterclaim Defendant AstraZeneca LP is a limited partnership operating and existing under the laws of the State of Delaware, with its principal place of business at 1800 Concord Pike, Wilmington, Delaware 19803. (*See* DE 1, ¶3).

49. Counterclaim Defendant Pozen Inc. is a corporation operating and existing under the laws of the State of Delaware, with its principal place of business at 1414 Raleigh Road, Chapel Hill, North Carolina, 27517. (*See* DE 1, ¶4).

JURISDICTION AND VENUE

50. This is an action for declaratory judgment pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, together with such further and other relief that may be necessary or proper. The basis for declaratory judgment is an actual controversy between DRL and AstraZeneca arising under the United States Patent Laws, Title 35 of the United States Code. This Court has subject matter jurisdiction over the action based on 28 U.S.C. §§ 1331 and 1338.

51. This Court has personal jurisdiction over AstraZeneca in that, *inter alia*, AstraZeneca voluntarily filed, in this Court, the Complaint giving rise to this Counterclaim, and because AstraZeneca is doing business in this district.

52. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(b) and (c) and/or § 1400(b).

The Asserted Patent

53. The U.S. Patent No. 6,926,907 (“the ‘907 patent”), entitled “Pharmaceutical Compositions for the Coordinated Delivery of NSAIDs,” issued on August 9, 2005 and lists John R. Plachetka as an inventor.

54. On information and belief, Pozen Inc. is the current owner by assignment of the ‘907 patent.

The Actual Controversy Concerning the Asserted Patent

55. An actual and justiciable controversy exists regarding the asserted patent by virtue of AstraZeneca’s Complaint. Thus, an actual controversy exists between AstraZeneca and DRL as to whether there is any valid claim of the asserted ‘907 patent that has been or could be infringed by the manufacture, use and/or sale of either DRL’s proposed product or an active pharmaceutical ingredient of the DRL’s proposed product supplied by DRL to a third party or whether DRL’s proposed product infringes certain claims of the ‘907 patent. DRL requires an immediate declaration of its rights vis-à-vis AstraZeneca with respect to the asserted patent.

First Counterclaim
Declaratory Judgment of Non-infringement (‘907 Patent)

56. DRL repeats and realleges the allegations contained in paragraphs 1-56 as if fully set forth here.

57. This counterclaim is for a declaration that DRL’s proposed product does not infringe at least claims 2-4, 6-8, 18-20, 25-27, 30-31, 36, 38-40, 43-44, and 49 of the ‘907 patent.

Second Counterclaim
Declaratory Judgment of Invalidity ('907 Patent)

58. This counterclaim is for a declaration that at least claims 1, 5, 9-17, 21-24, 28-29, 32-35, 37, 41-42, 45-48, and 50-55 of the '907 patent are invalid under Title 35 United States Code, including *inter alia* §§101, 102, 103, 112, and for double patenting.

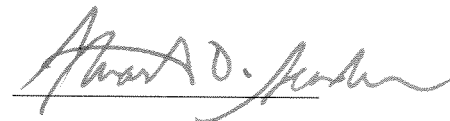
PRAYER FOR RELIEF

WHEREFORE, DRL prays for relief as follows:

- (a) That the Complaint against DRL be dismissed in its entirety and with prejudice and that the Plaintiffs take nothing thereby;
- (b) That the Court permanently enjoin Plaintiffs from asserting the '907 patent against DRL or the purchasers of its proposed product;
- (c) That this case be deemed to be an exceptional case within the meaning of 35 U.S.C. § 285;
- (d) That DRL be awarded its attorney fees and costs and expenses of the suit, and;
- (e) That the Court award other and further relief as it deems just and proper.

Dated: June 27, 2011

By:



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CERTIFICATION PURSUANT TO L. CIV. R. 11.2

Pursuant to Local Civil Rule 11.2, I hereby certify that upon information and belief, the matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding.

Dated: June 27, 2011

By:



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Reddy's Laboratories, Inc.*

CERTIFICATE OF SERVICE

I, Stuart Sender, do hereby certify that on June 27, 2011 I caused to be served a true and correct copy of ANSWER OF DR. REDDY'S LABORATORIES, LTD. AND DR. REDDY'S LABORATORIES, INC. AND COUNTERCLAIMS; RULE 7.1 DISCLOSURE STATEMENT; and CERTIFICATION PURSUANT TO L. CIV. R. 11.2 by ECF and by Federal Express in properly addressed envelope(s) to:

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Dated: June 27, 2011

By:

A handwritten signature in black ink, appearing to read "Andrew J. Miller", written over a horizontal line.

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